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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/923,444      | 08/08/2001  | Yi Li                | PF116D1C1           | 9646             |

22195 7590 03/06/2003  
HUMAN GENOME SCIENCES INC  
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ROCKVILLE, MD 20850

[REDACTED] EXAMINER

ALLEN, MARIANNE P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631     |              |

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/923,444             | LI ET AL.           |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Marianne P. Allen      | 1631                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 20 December 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-29 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

In view of applicant's concern regarding the format of the prior restriction requirement (Paper No. 5, mailed 11/29/02), it is hereby vacated in view of the following restriction requirement. Newly presented claims 24-29 are included.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to isolated polynucleotides and a method of producing the encoded protein, classified in class 435, subclass 69.1.
- II. Claims 14-15, 21, and 24-29, drawn to isolated polypeptides, classified in class 530, subclass 350.
- III. Claim 16, drawn to an antibody, classified in at least class 530, subclass 387.1, for example.
- IV. Claim 17, drawn to antagonist/inhibitors of a polypeptide, classified in at least class 530, subclass 324, for example.
- V. Claim 18, drawn to an agonist of polypeptide, classified in at least class 530, subclass 24, for example.
- VI. Claim 19, drawn to a method of treating with an agonist, classified in class 514, subclass 12.
- VII. Claim 20, drawn to a method of treating with an antagonist, classified in class 514, subclass 12.
- VIII. Claim 22, drawn to a method of gene therapy, classified in class 514, subclass 44.
- IX. Claim 23, drawn to methods of screening, classified in class 435, subclass 7.1.

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The inventions are distinct, each from the other because of the following reasons:

The products of groups I-V are structurally distinct polynucleotides, polypeptides, agonists, antibodies, and antagonists/inhibitors and would require non-coextensive literature searches. The methods of groups VI -IX are distinct, each from the other, because they have different method steps, starting materials, and/or goals. They would require non-coextensive literature searches. The products are distinct from the methods as they can be used in a variety of methods as demonstrated by the claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Marianne P. Allen*  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa  
March 5, 2003